

Docket No.: 284112US0PCT

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF: :
ATSUSHI YAMAGISHI, et al. : EXAMINER: SUTTON, D.C.
SERIAL NO.: 10/564,368 :
FILED: JANUARY 12, 2006 : ART UNIT: 1612
FOR: ORAL ACTIVITY COMPOSITION

DECLARATION UNDER 37 C.F.R. § 1.132

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313

Sir:

Now comes Mr. Atsushi Yamagishi who deposes and states that:

1. I am a graduate of the Graduate School of Nagaoka University of Technology, Materials Science and Technology, and received my Master's degree in the field of Materials Science and Technology, in the year 1988.
2. I have been employed by Kao Corporation, for 20 years involved in research and development of hair care products from 1988 to 1989 and then involved in research and development of oral products from 1989 to present.
3. I understand the English language or, at least, that the contents of the Declaration were made clear to me prior to executing the same.
4. The following experiments were carried out by me or under my direct supervision and control.
5. The following experimental procedure was followed:

Examples 1, 2 and 5

Alternately applying (A) and (B)

HAP pellets (10 mm x 10 mm x 2mm) were treated for 10 seconds with 10 ml of the first composition A, and then with 10 ml of the composition B for another 10 seconds. “1 min” of Table means that this process was repeated three times, and “3 min.” means that this process was repeated 9 times.

Simultaneously applying (A) and (B)

The composition B was added to the composition A at the last minute before use (i.e., “mixed at teeth”). Then, HAP pellets (10 mm x 10 mm x 2mm) were immersed in the solution including the composition A and the composition B. “1 min” of Table means that HAP pellet was treated with the solution for 1 minute, and “3 min.” means that HAP pellet was treated with the solution for 3 minute.

Pre-mixing (A) and (B)

The composition A and the composition B were mixed well before use. Then, HAP pellets (10 mm x 10 mm x 2mm) were immersed in the mixture. “1 min” of Table means that HAP pellet was treated with the mixture for 1 minute, and “3 min.” means that HAP pellet was treated with the mixture for 3 minute.

Example 3

Alternately applying (A) and (B)

10 ml of purified water was included into swab and then the composition B was added into the swab to be solved. HAP pellets (10 mm x 10 mm x 2mm) were treated for 10 seconds with 10 ml of the first composition A, and then with the swab including the composition B

for another 10 seconds. “1 min” of Table means that this process was repeated three times, and “3 min.” means that this process was repeated 9 times.

Simultaneously applying (A) and (B)

10 ml of purified water was included into swab and then the composition B was added into the swab to be solved. 10 ml of composition A was poured the swab. Then, HAP pellets (10 mm x 10 mm x 2mm) were treated with the solution excluded from the swab. “1 min” of Table means that HAP pellet was treated with the solution for 1 minute, and “3 min.” means that HAP pellet was treated with the solution for 3 minute.

Pre-mixing (A) and (B)

10 ml of purified water was included into swab and then the composition B was added into the swab to be solved. 10 ml of composition A was poured the swab and the swab was squeeze out well. Solution excluded and squeezed from the swab was mixed well. Then, HAP pellets (10 mm x 10 mm x 2mm) were treated with the mixture. “1 min” of Table means that HAP pellet was treated with the mixture for 1 minute, and “3 min.” means that HAP pellet was treated with the mixture for 3 minute.

Example 4

The composition B was solved by equal amount of water. The testing regarding Alternately applying (A) and (B), Simultaneously applying (A) and (B), and Pre-mixing (A) and (B) were conducted in the same manner as Example 1

6. The following results were obtained as a measure of fluorine uptake ($\mu\text{g}/\text{cm}^2$):

	Alternately applying (A) and (B) ⁱ		Simultaneously applying (A) and (B) ⁱⁱ		Pre-mixing (A) and (B) ⁱⁱⁱ	
	1 min.	3 min.	1 min.	3 min.	1 min.	3 min.
Example 1	5.2	13.5	0.3	0.4	0.1	0.2
Example 2	5.8	15.8	0.6	0.6	0.2	0.2
Example 3	4.9	11.5	0.8	0.9	0.3	0.4
Example 4	0.6	5.2	0.2	0.2	0.1	0.1
Example 5	0.3	3.8	0.1	0.1	0.1	0.1

i) Alternately applying (A) and (B): alternately at 10 second intervals

ii) Simultaneously applying (A) and (B): mixed at teeth

iii) Pre-mixing (A) and (B): pre-mixed for 10 seconds prior to application to teeth

7. That the foregoing results show the method of the present application where compositions (A) and (B) are alternately applied to teeth provides a substantial advantage as compared to either simultaneous application of compositions (A) and (B) or pre-mixing compositions (A) and (B) prior application to the tooth. This striking and considerable advantage in fluorine uptake by alternate application far exceeds any difference that could have been expected and, as such, represents an unexpected discovery.

8. I declare further that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

9. Further Declarant saith not

Atsushi Yamagishi
Name:

June 26, 2008
Date